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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,558	06/17/2005	Yitzchak Hillman	30082	9264

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EXAMINER	
EPPS FORD, JANET L	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
08/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,558	HILLMAN, YITZCHAK	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *100-121* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *100-121* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group (a), claim(s) 100-112, drawn to an article of manufacture and a method of treating a disease in a subject in need thereof, the method comprising providing to the subject a therapeutically effective amount of a compound being capable of decreasing an activity and/or level of an antimicrobial peptide (AMP) and/or AMP-like molecule, thereby treating the disease in the subject in need thereof, wherein said compound is a molecule capable of binding said AMP or AMP-like molecule, and wherein said molecule is an antibody or an antibody fragment.

Group (b)-(i), claims 100-101, 103-107, and 109-112 drawn to an article of manufacture and a method of treating a disease in a subject in need thereof, the method comprising providing to the subject a therapeutically effective amount of a compound being capable of decreasing an activity and/or level of an antimicrobial peptide (AMP) and/or AMP-like molecule, thereby treating the disease in the subject in need thereof, wherein said compound is a:

(b) an enzyme capable of cleaving said AMP and/or AMP-like molecule;

(c) an siRNA molecule capable of inducing degradation of an mRNA encoding said AMP and/or AMP-like molecule;

(d) a DNAzyme capable of cleaving an mRNA or DNA encoding said AMP and/or AMP-like molecule;

(e) an antisense, polynucleotide capable of hybridizing with an mRNA encoding said AMP and/or AMP-like molecule;

(f) a ribozyme capable of cleaving an mRNA encoding said AMP and/or AMP-like molecule;

(g) a non-functional analogue of at least a functional portion of said AMP and/or AMP-like molecule;

(h) a molecule capable of inhibiting activation or ligand binding of said AMP and/or AMP-like molecule; and

(i) a triplex-forming oligonucleotide capable of hybridizing with a DNA encoding said AMP and/or AMP-like molecule.

Group (j), claims 113-121 drawn to a method of treating a disease in a subject in need thereof, comprising providing to the subject a therapeutically effective amount of an antimicrobial peptide (AMP) and/or AMP-like molecule, thereby treating the disease in the subject in need thereof.

2. The inventions listed as Groups (a)-(j) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Invention groups (a)-(j) are drawn to patentably distinct method comprising the administration of patentably distinct therapeutic agents having distinct modes of operation as defined above in groups (a)-(j), and potentially having a plurality of distinct chemical structures, wherein each distinct structure requires a separate search and consideration of the prior art.
3. The multiple methods as set forth in groups (a)-(j) each comprise the use of a structurally and functionally distinct product, therefore the multiple products are considered to encompass multiple categories of invention as defined in 37 CFR § 475(b). Therefore, the inventions as defined in groups (a)-(j) are directed to multiple categories of invention and are therefore considered to lack unity of invention as per 37 CFR 1.475(c).

§ 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.
(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claims 110, 116, and 120 recite multiple species of AMP and/or AMP-like molecules: beta-defensin-1, beta-definsin-2, and LL-37. The multiple species of AMP and/or AMP-like molecules are drawn to structurally distinct molecules comprising a distinct chemical structure, and requiring a separate search and consideration of the prior art. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The separate compounds are drawn to the use of multiple products and are considered to lack unity of invention since they claims are drawn to distinct categories of invention.

Claims 105, 111, 117, and 121 recite multiple species of disease: tumor, epithelial disease, skin disease, gastrointestinal disease, and an endothelial disease. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The multiple methods for the treatment of the multiple species of diseases recited in the instant claims are also considered to lack unity of invention since they comprise distinct methods, and therefore are considered to encompass multiple categories of invention.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The following claim(s) are generic: 100-102, 106-108, 113-114, and 118 are generic.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner
Art Unit 1633

JLE